REMARKS

Claims 28 to 38 are all the claims pending in the application, prior to the present Amendment.

Applicants have amended independent claims 28 and 29 to incorporate the recitations of claim 35. Applicants have canceled claims 31 to 36.

Claims 36 and 37 have been rejected under the second paragraph of 35 U.S.C. § 112 as indefinite.

With respect to claim 36, applicants inadvertently did not cancel this claim in the Amendment Under 37 C.F.R. § 1.116 filed on March 16, 2009. Accordingly, applicants have now canceled claim 36, thereby overcoming this aspect of the rejection.

With respect to claim 37, which recites that the fatigue recited in claims 28 and 29 is muscle fatigue, the Examiner states that claim 37 does not further narrow the subject matter of claims 28 and 29. Claims 28 and 29 recite that the fatigue is either (1) physical exhaustion caused by exercise, or (2) caused by aging.

Applicants submit that the muscle fatigue recited in claim 37 is a further limitation on the fatigue (2) caused by aging.

In particular, the "fatigue caused by aging" recited in claims 28 and 29 includes fatigue caused by brain work and light duty work, etc., as well as muscle fatigue. Claim 37 further narrows the subject matter of the fatigue caused by aging recited in claims 28 and 29 to muscle fatigue.

In view of the above, applicants request withdrawal of this rejection.

Claims 28 to 35 and 38 have been rejected under 35 U.S.C. § 103(a) as obvious over WO 2002/092067 to Fuji et al in view of the Wilson et al publication, and further in view of the newly cited excerpt from Remington's Pharmaceutical Sciences (Fifteenth Edition, 1980, page 712).

Applicants submit that these documents do not disclose or render obvious the subject matter of the presently amended claims and, accordingly, request withdrawal of this rejection.

The present invention as set forth in claim 28 as amended above is directed to a method for reducing fatigue in animals in the state of fatigue, wherein the animals are middle aged or older persons, and wherein the fatigue is physical exhaustion by exercise or fatigue caused by aging, which comprises administering, to said animals, a fatigue reducing agent comprising reduced coenzyme Q represented by formula (1) of claim 28 as an active ingredient.

The present invention as set forth in claim 29 as amended above is directed to a method for reducing fatigue in animals by administering a fatigue reducing agent, wherein the animals are middle aged or older persons, and wherein the fatigue is caused by exercise or fatigued caused by aging, and recites that the fatigue reducing agent comprises the reduced coenzyme Q of formula (1) and oxidized coenzyme Q of formula (2).

Thus, applicants have amended claims 28 and 29 to recite that the animals are middle aged or older persons. Support for this amendment can be found in the present specification at page 8, lines 10 to 15.

As applicants have previously stated, there are two kinds of fatigue, the one physiological, the other pathological. Physiological fatigue manifests in a healthy individual without underlying diseases when the amount of activity exceeds a certain level and it can be

naturally relieved by rest. On the other hand, pathological fatigue manifests in patients with a physical disorder, such as cancer and AIDS, a mental disorder such as depression, and sleep disorder and/or a continual weariness, such as chronic fatigue syndrome, and it cannot be naturally relieved by rest alone. Namely, "fatigue" occurs in a wide variety of situations.

It is technically known that the effects on fatigue and methods of dealing with fatigue vary depending on the nature and cause of the fatigue. In the present invention, " reducing fatigue" aims to maintain one's stamina and good health in daily life, as described in the Abstract, Background Art and the like in the present specification. In other words, the object of the present invention is reduction of physiological fatigue, rather than reduction of extreme fatigue due to severe disease, or pathological fatigue. Fujii et al merely disclose that reduced coenzyme Q is effective for specific diseases.

The method of the present invention does not aim at reducing pathological fatigue caused by the diseases recited in Fujii et al. In addition, Fujii et al do not teach that pathological fatigue caused by diseases can be reduced by administration of reduced coenzyme Q.

As mentioned above, inasmuch as the "physical exhaustion caused by exercise or fatigue caused by aging", which is the target in the present invention, is completely different in the cause and mechanism from the pathological severe fatigue due to the diseases recited in Fujii et al, and inasmuch as Fujii et al do not teach that pathological severe fatigue can be decreased by reduced coenzyme Q, the effect of the present invention cannot be arrived at from the teachings of Fujii et al.

Wilson discloses that patients with heart failure are limited by exertional fatigue during both normal daily activities and maximal exercise. Therefore, exertional fatigue in heart failure

patients disclosed in Wilson can be clearly distinguished from the "physiological fatigue" in healthy people during daily life and exercise.

In the treadmill test performed in Examples 3 and 4 of the present specification, rats were forced to run on a belt conveyor, where the level of fatigue can be varied by changing the running speed. Under the conditions adopted in the Examples of the present specification, i.e., running with a speed of 10m/min (for 14-15 minutes in Example 4) with a speed increase by 5 m/min every 3 minutes, the rats after running recovered in a relatively short time of about 1 hour and could move almost as usual.

In Examples 1 and 2 of the present specification, it was confirmed that, in comparison to oxidized coenzyme Q, reduced coenzyme Q further increases the amount of coenzyme Q in the muscle, which means that reduced coenzyme Q provides a higher effect on the muscular fatigue. However, Fujii et al, Wilson et al and Remington's do not describe or suggest that reduced coenzyme Q specifically increases the level of coenzyme Q in the muscle.

In Example 4 of the present application, an unexpectedly remarkable effect was achieved in a treadmill test using aged rats, in that reduced coenzyme Q provided a maximum running time-prolonging effect of not less than 7 times that of oxidized coenzyme Q. This effect is an unexpected effect and did not occur in young rats, as can be seen in Comparative Example 3 of the present specification.

As discussed above, applicants have amended claims 28 and 29 to direct them to "middle-aged and older persons." Reduced coenzyme Q has a remarkable effect of reducing the fatigue in middle-aged and older persons for whom oxidized coenzyme Q is unlikely to prove effective. This effect in middle-aged and older persons is not described or suggested in the cited

references, and cannot be conceived by those skilled in the art from the disclosures of the cited references.

In view of the above, applicants request withdrawal of this rejection.

Claims 28, 30, 32 and 33 have been provisionally rejected on the grounds of nonstatutory double patenting as being unpatentable over claims 6 and 10 to 19 of copending U.S. Application No. 11/596,059.

Claim 35 has not been subject to this rejection. As discussed above, applicants have amended claim 28 to incorporate the subject matter of claim 35.

Applicants submit that this rejection has been overcome in view of the above amendment to incorporate the recitations of claim 35 into claim 28.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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